

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/200,657 11/25/98 HEIN

M TSRI-184.200

EXAMINER

HM12/0705

THOMAS FITTING  
THE SCRIPPS RESEARCH INSTITUTE  
10550 NORTH TORREY PINES ROAD  
MAIL DROP-TPC-8  
LA JOLLA CA 92037

BUI, P

ART UNIT

PAPER NUMBER

1638

DATE MAILED:

07/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
**09/200,657**

Applicant(s)

H in t al.

Examiner

**Phuong Bui**

Art Unit

**1638**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1) ☒ Responsive to communication(s) filed on Apr 12, 2001

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

4) ☒ Claim(s) 21, 32-54, 56-66, and 68-82 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 21, 32-54, 56-66, and 68-82 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirements.

## Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some\* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 18

20) ☐ Other:

Art Unit: 1638

### **DETAILED ACTION**

1. Receipt is acknowledged of Applicant's Response, Amendment C, Terminal Disclaimer and Supplemental Information Disclosure Statement filed April 12, 2001. New claims 79-82 have been entered. Accordingly, claims 21, 32-54, 56-66 and 68-82 are pending and are examined in the instant application. A new Office action having new grounds of rejection is set forth below. Sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Specification***

2. The amendment updating the status of Applicant's cross-references to related applications has been entered. The recitation of "the disclosures of which are incorporated by reference herein" should be deleted because such incorporation may constitute new matter.

#### ***Information Disclosure Statement***

3. An initialed and dated copy of Applicant's IDS form 1449, Paper No. 18, filed April 12, 2001 is attached to the instant Office action.

#### ***Double patenting***

4. The provisional rejection of claims 21 and 32-78 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21-30 and 36-37 of copending Application No. 09/199534 has been overcome by Applicant's filing of the Terminal Disclaimer on April 12, 2001. Thus, this provisional rejection is hereby **withdrawn**.

5. The provisional rejection of claims 21 and 32-78 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21-64 of copending

Art Unit: 1638

Application No. 09/512568 has been overcome by Applicant's filing of the Terminal Disclaimer on April 12, 2001. Thus, this provisional rejection is hereby **withdrawn**.

6. The rejection of claims 21 and 32-78 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-12 of U.S. Patent No. 5,959,177 has been overcome by Applicant's filing of the Terminal Disclaimer on April 12, 2001. Thus, this provisional rejection is hereby **withdrawn**.

7. The rejection of claims 21 and 32-78 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 5,202,422 has been overcome by Applicant's filing of the Terminal Disclaimer on April 12, 2001. Thus, this provisional rejection is hereby **withdrawn**.

#### *New Grounds of Rejection*

8. Claims 21, 32-54, 56-66, and 68-82 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21-66 of copending Application No. 09/512736. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the claims of the instant application are fully encompassed by the copending claims. The heavy chain and/or light chain of the antibody renders obvious the immunoglobulin molecules and glycopeptide multimers. Further, Fab, Fab', F(ab)2, Fv and J chain were well known antibody components. Thus, the claims of the instant application are rendered obvious by the copending claims.

Art Unit: 1638

***Claim Rejections - 35 USC § 112, second paragraph***

9. The rejection of claims 42, 55 and 67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is hereby **withdrawn** in view of Applicant's amendments.

***Claim Rejections - 35 USC § 102***

10. The rejection of claims 21, 32-39, 42-47, 49-54, 56, 57, 60-66, 68, 70-75, 78, and 80-82 under 35 U.S.C. 102(b) as being anticipated by During (Dissertation, July 9, 1988, University of Koln, FRG, English translation) is hereby **maintained** for reasons of record.

Applicant's arguments have been fully considered, but were not found persuasive. Applicant asserts that During fails to anticipate the claimed invention as it fails to disclose transgenic plants including the claimed nucleotide sequences or the immunoglobulin products generated thereby. Applicants further assert that During fails to teach the requirement for cleavage of the leader sequence as is now claimed. Finally, Applicant asserts that During is non-enabling with regard to the production of an assembled, functional immunoglobulin in plant cells.

Regarding the assertion that During fails to teach the claimed nucleotide sequences or immunoglobulin products made therefrom, the Office notes that the claims do not recite specific nucleotide sequences. Thus, this argument is not germane to the claimed invention. Though the claims do recite a variety of immunoglobulin products, it is not clear which of these products set forth in one of the above included claims is not taught by During. During teaches the production of immunoglobulin molecules having both heavy and light chains.

Art Unit: 1638

Regarding Applicant's assertion of non-enablement of During, the Office notes that the burden of establishing non-enablement is Applicant's. In order to carry this burden, Applicant must produce evidence leading to the conclusion that one skilled in the art would have reasonably doubted that the teaching of the reference would lead one skilled in the art to be able to make and use the disclosed subject matter in question. This standard does not require the reference to "unquestionably" support the conclusions of the reference. Here, Applicant merely sets forth argument directing attention to portions of the During document. Applying this standard to these portions does not lead to the conclusion that the During document is non-enabling. The lack of corroboration that the Ac38 antibody is fully functional in itself does not lead to the conclusion that this antibody is in fact non-functional. Moreover, whether During required extremely sensitive assays for the presence of antibodies does not call the entire project into question. Again, to do so is to misapply the standard above. Finally, the fact that During suggests that additional experimentation is needed to confirm the results and/or to learn more about the nature of the expression and assembly of antibodies in plants also does not serve to establish non-enablement of this reference. It is common for researchers to raise questions and areas for further study when publishing their work. Such statements are not meant to show that the researchers' conclusions are wrong and that <sup>their</sup> ~~the~~ work cannot be duplicated with success. Thus, it is clear that Applicant has not carried the burden of establishing non-enablement of During.

Art Unit: 1638

11. The rejection of claims 21, 32-40, 42-47, 49-54, 56-58, 60-66, 68, 70-76, and 78-82 under 35 U.S.C. 102(e) as being anticipated by Goodman (US Pat. No. 4956282) is hereby **maintained** for reasons of record.

Applicant's arguments have been fully considered, but were not found persuasive. Applicant asserts that Goodman also is non-enabled. Keeping in mind the standard set forth in the rejection above for an applicant to establish that a reference is non-enabled, the position of the Office is that Goodman may only be considered non-enabling for the production of fully assembled, complete antibodies when applied to claims of this scope. As none of the instant claims to which Goodman was applied recite the production of fully assembled, complete antibodies, Applicant's arguments must fail. In particular, Applicant notes that Goodman expresses single chain polypeptides in plant. Claims 44 and 66 specifically recite that the immunoglobulin molecule is only a single chain. Accordingly, Applicant's arguments regarding Goodman are not commensurate in scope with the claims.

***Claim Rejections - 35 USC § 103***

12. The rejection of claims 21, 32-54, 56-66, and 68-82 under 35 U.S.C. 103(a) as being unpatentable over During (Dissertation, July 9, 1988, University of Koln, FRG, English translation) in view of Applicant's admitted prior art is hereby **maintained** for reasons of record.

Applicant's arguments have been fully considered, but were not found persuasive. Applicant asserts that cell secretion in During is not observed as no association of antibody with the cell wall is observed. However, During teaches a leader sequence allowing for secretion of

Art Unit: 1638

the expressed immunoglobulin molecule. Moreover, though Applicant argues that the During strategy is not commercially applicable, no such requirement is made either by the patent laws or by the instant claims. The only claim requiring a particular level of expression, claim 79, itself does not require that the expressed molecule be a fully assembled, complete antibody. Finally, since During teaches that fully assembled antibodies are produced, cleavage of the leader must have occurred. In addition, During discusses leader cleavage strategies thus suggesting to one of ordinary skill in the art other approaches to ensuring that the secretion signal would and should be cleaved.

13. The rejection of claims 21, 32-54, 56-66, and 68-82 under 35 U.S.C. 103(a) as being unpatentable over Goodman (US Pat. No. 4956282) in view of Applicant's admitted prior art is hereby **maintained** for reasons of record.

Applicant's arguments have been fully considered, but were not found persuasive. The comments set forth above are reiterated here. The instant claims do not all require fully assembled, complete antibodies that have been produced from plant cells. Thus, significantly, though the invention disclosed may require correct post-expression processing of expressed heavy and light chains, the claims do not make this requirement.

***Remarks***

14. No claim is allowed.

15. **THIS ACTION IS MADE FINAL.** Applicant's amendment necessitated the new grounds of rejection. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



Art Unit: 1638

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


16. Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Bui whose telephone number is (703) 305-1996. The Examiner can normally be reached Monday-Friday from 6:30 AM - 4:00 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Paula Hutzell, can be reached at (703) 308-4310.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Phuong Bui  
Primary Examiner  
Group Art Unit 1638  
June 30, 2001

  
**PHUONG T. BUI**  
**PRIMARY EXAMINER**